IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. JMA PARTNERS, INC., a corporation d/b/a GUARDIAN PHARMACY SERVICES, and JACK R. MUNN, an individual Defendants.	)	Civil Action No. 3:19-cv-553 **COMPLAINT FOR INJUNCTION**

The United States of America, Plaintiff, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and this court's inherent equitable authority, to permanently enjoin the defendants, JMA Partners, Inc., a corporation d/b/a Guardian Pharmacy Services ("Guardian"), and Jack R. Munn, an individual (collectively, "Defendants") from: (a) violating 21 U.S.C. § 331(a) by introducing and/or causing to be introduced, or delivering and/or causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and/or 351(a)(2)(B) and/or misbranded within the meaning of 21 U.S.C. §§ 352(a)(1) and/or 352(f)(1); (b) violating 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and/or 351(a)(2)(B) and/or misbranded within the meaning of 21 U.S.C.

§§ 352(a)(1) and/or 352(f)(1) while such drugs are held for sale after shipment of one or more of their components in interstate commerce; and (c) violating 21 U.S.C. § 331(d) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

2. Defendants have a history of manufacturing sterile and non-sterile drug products under conditions that fall short of the minimum requirements to ensure safety and quality. The history of serious violations of the Act, and the likelihood that violations will continue in the absence of court action, demonstrate that permanent injunctive relief is necessary.

Jurisdiction and Venue

3. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

4. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

Defendants and Their Operations

5. JMA Partners, Inc. ("JMA") is a Texas corporation d/b/a Guardian Pharmacy Services located at 7920 Elmbrook Drive, Suite 108, Dallas, Texas, 75247, within the jurisdiction of this Court. JMA was incorporated in 1997 and assumed the name Guardian Pharmacy Services in 2011. JMA obtained a pharmacy license from the Texas State Board of Pharmacy in 1997 for compounding sterile and non-sterile drug products, including compounding drugs for "office use." JMA also has had licenses (pharmacy, wholesaler, manufacturer, and/or distributor licenses, depending on state regulations) in other states and the District of Columbia, including Arizona, Colorado, Iowa, Kansas, Maryland, Washington, Missouri, Montana, Oklahoma, and Wisconsin.

6. Jack R. Munn has owned Guardian since its inception. Defendant Munn is a Texas state-licensed pharmacist and the person most responsible for Guardian's operations. Defendant Munn retains all financial and operational authority over the business, including the ability to prevent, detect, and correct violations. Defendant Munn was present on each day of FDA's 2016 and 2018 inspections. Defendant Munn performs his duties at Guardian, within the jurisdiction of this Court.

7. During their regular course of business, Defendants manufacture, process, pack, label, hold, and distribute articles of drug, within the meaning of 21 U.S.C. § 321(g)(1). Until recently, the majority of Defendants' drug products, by virtue of their labeling and/or route of administration, purport to be or are intended to be sterile. Sterile drugs include drugs that are required to be sterile under Federal or state law or drugs that, by nature of their intended use or method of administration, are expected to be sterile ("sterile drugs"). *See* 21 U.S.C. § 353b(d)(5). Defendants' sterile drugs are administered and/or injected into patients via the following methods: intrathecal (into the spinal canal), intravitreal (into the eye), and epidural (into the space outside the spinal cord's dura mater).

8. Defendants used two different methods to aseptically process their sterile drug products. Most of Defendants' sterile drug products were processed via filtration with aseptic processing, which involves filling drug products that have been rendered sterile by filtration into final containers in a manner that maintains sterility. The remaining sterile drug products were processed via terminal sterilization, which involves treatment of the drug solution in its final container closure system with heat in an autoclave or dry heat oven.

9. Defendants' facility contains a "cleanroom suite" where, until recently, it produced purportedly sterile drugs. The cleanroom suite contains three "ISO 5" processing areas

within an "ISO 7" buffer room, which is connected to an "ISO 8" ante room via motion-sensored doors ("ISO" refers to International Standards Organization classifications for cleanrooms). ISO 5 processing areas are critical zones that, by designation, have the highest level of cleanliness within the facility. Defendants' ISO 5 areas purport to have sufficient protection from contamination during the aseptic processing of sterile drugs.

10. Defendants have distributed their drugs to patients pursuant to valid prescriptions for individually identified patients or directly to hospitals and other health care entities without valid prescriptions for individually identified patients ("office stock") in Texas and throughout the United States, including some shipments to California, Oklahoma, and New York.

11. FDA inspections in 2016 and 2018 revealed that approximately half of Defendants' compounded drug products were distributed without valid prescriptions for individually identified patients.

12. Defendants manufacture drugs at Guardian using components that were shipped in interstate commerce, including components from New York and Alabama.

Requirements of the Act

13. Under the Act, a "drug" includes any article that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. § 321(g)(1)(B), or that is "intended to affect the structure or any function of the body . . . ," 21 U.S.C. § 321(g)(1)(C).

14. A drug is deemed to be adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 351(a)(2)(A).

15. The Act also requires that drugs be manufactured in accordance with the current good manufacturing practice ("CGMP") requirements. 21 U.S.C. § 351(a)(2)(B); 21 C.F.R. § 210.1(b). A drug is deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with CGMP to assure that it meets the requirements of the Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess, regardless of whether the drug is actually defective in some way. FDA has promulgated CGMP regulations for drugs and finished pharmaceuticals. 21 C.F.R. Parts 210 and 211.

16. A drug is misbranded if its labeling is "false or misleading in any particular." 21 U.S.C. § 352(a)(1).

17. A drug is misbranded within the meaning of 21 U.S.C. § 352(f)(1) if its labeling fails to bear "adequate directions for use" and it does not fall within a regulatory exemption from that requirement. FDA has defined "adequate directions for use" as "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5.

18. A "new drug" includes any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). For a product to be deemed "generally recognized as safe and effective", it must have substantial evidence of safety and effectiveness.

19. A drug that is a "new drug" within the meaning of the Act is prohibited from being introduced or delivered into interstate commerce unless FDA has approved a new drug

application ("NDA") or abbreviated new drug application ("ANDA") for that drug, or the drug is exempt from approval under an investigational drug application. 21 U.S.C. §§ 331(d) and 355.

Exemptions in the Act for Compounded Drugs

20. Compounding generally refers to the practice in which a licensed pharmacist or physician combines, mixes, or alters ingredients of a drug to create a drug. Compounded drugs generally are tailored to the needs of identified individual patients.

21. Under the Act, 21 U.S.C. § 353a, compounded drugs may be exempt from three specified provisions of the Act: CGMP requirements (21 U.S.C. § 351(a)(2)(B)); "adequate directions for use" in labeling (21 U.S.C. § 352(f)(1)); and approval of new drugs for humans (21 U.S.C. § 355). These exceptions are applicable to compounded drugs that comply with all of the conditions set forth in 21 U.S.C. § 353a.

22. Among other things, section 353a requires that the drug product be "compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient . . . ." 21 U.S.C. § 353a(a). Moreover, the compounding must be by a licensed pharmacy or physician either "on the prescription order for such individual patient," or "in limited quantities before the receipt of a valid prescription order for such individual patient" and "is based on a history of" the pharmacist or physician "receiving valid prescription orders for the compounding of the drug product . . . ." 21 U.S.C. § 353a(a)(1) & (2). Drug products distributed without patient-specific prescriptions are referred to as "office stock" or compounded for "office use."

23. Whereas drugs compounded in compliance with the conditions set forth in 21 U.S.C. § 353a are exempt from three specific requirements under the Act, such compounded

drugs remain subject to all of the Act's other applicable adulteration and misbranding provisions. For instance, compounded drugs are not exempt from the provision that drugs are adulterated if they are prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health in violation of 21 U.S.C. § 351(a)(2)(A), or are misbranded if they contain false or misleading labeling in violation of 21 U.S.C. § 352(a).

FDA's Most Recent Inspection at Guardian

24. FDA conducted its most recent inspection at Guardian between April 2 and 20, 2018 ("2018 Inspection") as a follow-up to a previous violative inspection in 2016 that resulted in a November 2017 Warning Letter. FDA investigators listed their observations in a Form FDA-483, List of Inspectional Observations ("FDA-483"), which was provided to Defendant Munn at the conclusion of the inspection. The FDA investigators discussed each of the inspectional observations with Defendant Munn.

25. During the 2018 Inspection, FDA investigators documented that Defendants compounded approximately 576 human drug products between January 1 and March 31, 2018. Of these 576 compounded human drug products, approximately 51% did not have patient-specific prescriptions prior to distribution. The absence of patient-specific prescriptions for 51% of their products meant that Defendants did not meet the conditions of section 353a, and were therefore not exempt from the CGMP, new drug approval, and adequate directions for use requirements for its sterile drugs at the time of the 2018 Inspection.

Adulteration Based on Insanitary Conditions

26. During the 2018 Inspection, FDA investigators observed and documented numerous insanitary conditions whereby Defendants' drugs may become contaminated with filth or rendered injurious to health, including, but not limited to, the following:

A. Failure to certify systems used to maintain adequate air quality in cleanroom suite. Defendants failed to certify the systems used to maintain the air quality in the ISO 5 processing areas, and ISO 7 and ISO 8 cleanrooms since September 2017. All systems used to maintain air quality should be tested semi-annually to certify that they are performing adequately to reduce the risk that drugs are contaminated with airborne microorganisms.

B. Inadequate cleaning and sanitization of aseptic processing areas. Defendants failed to ensure that the aseptic processing areas are adequately cleaned and sanitized to reduce the risk of microbial contamination during manufacturing. Defendants routinely used non-sterile disinfectants and non-sterile wipes during cleaning of aseptic processing areas, in violation of Guardian's standard operating procedure. Non-sterile disinfectants were placed in dispensers labeled "Sterile IPA" and used throughout the facility. Defendants also failed to periodically use a sporicidal agent to disinfect the facility.

C. Inadequate equipment. Defendants used an ISO 5 laminar airflow hood for aseptic processing that was rusted in areas and taped. Another ISO 5 laminar airflow hood in the cleanroom was supported by non-porous particle board and covered with tape. Because of these alterations, Defendants' equipment was not appropriately designed to facilitate cleaning and maintenance.

D. Failure to take adequate corrective actions to ensure adequate levels of humidity in aseptic areas after unexplained discrepancies in room conditions. Defendants documented 61 instances between January 2017 and April 2018 that humidity in the cleanroom suite exceeded the necessary range of 30%-50% humidity, but failed to take adequate corrective actions after the unexplained discrepancies. High humidity levels can lead to an increase in the

proliferation of microorganisms present in the aseptic processing areas, which in turn can cause microbial contamination of drug products being processed in that area.

E. Failure to adequately simulate aseptic processes by performing media fills. Defendants had not conducted any media fill simulations since September 2017. The media fill simulations Defendants conducted prior to September 2017 did not simulate worst-case conditions because they simulated processing for fills of 100 syringes despite the fact that Guardian typically produced batches of 400 or more syringes. Compounding pharmacies should perform media fill simulations that represent their worst-case conditions at least semi-annually to demonstrate that operators are adequately performing aseptic processing of sterile drugs. These simulations are intended to represent the most difficult steps and operations of the fill. Because Defendants failed to simulate aseptic processes by performing a media fill simulation that adequately represents the worst-case scenario for the amount of sterile drugs they produce, they could not assure the sterility of their aseptically processed drugs.

27. The insanitary conditions that FDA investigators observed at Guardian's facility during the 2018 Inspection establish that drugs manufactured and distributed by Defendants were adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), in that they were prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health.

28. Defendants violated 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A).

29. Defendants violated 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

Adulteration Based on CGMP Violations

30. During the 2018 Inspection, FDA investigators documented significant deviations from the CGMP requirements in Defendants' sterile and non-sterile drug manufacturing operations, including but not limited to the following:

A. Failure to establish and follow an adequate system for monitoring environmental conditions in aseptic processing areas, as required by 21 C.F.R. § 211.42(c)(10)(iv). Defendants failed to conduct adequate environmental monitoring of the aseptic processing areas to reduce the risk of microbial contamination during manufacturing, in violation of Guardian's own standard operating procedure that required monthly monitoring. At the time of the 2018 Inspection, Defendants had not performed any environmental monitoring of ISO 5 areas or personnel in four months.

B. Failure to establish and follow appropriate written procedures, including validation of all aseptic and sterilization processes, designed to prevent microbial contamination of drug products purporting to be sterile, as required by 21 C.F.R. § 211.113(b). Defendants had not adequately validated the processes used to sterilize drugs or glassware. Guardian's autoclave record log between February 12 and March 15, 2018, indicated that Defendants had run 23 autoclave cycles without biological indicators, including nine different lots of drugs. Guardian's dry heat oven record log between January 4, 2017, and April 6, 2018, indicated that Defendants had run 285 dry heat cycles without a biological indicator, including eight different lots of drugs. Defendants failed to document the time and temperature at which the drugs were treated in the

autoclave and dry heat oven. Defendants also lacked appropriate written procedures for testing the integrity of the 0.22 micron filters that are used to produce sterile drugs.

C. Failure to establish and follow a written testing program designed to adequately assess whether each batch of purportedly sterile drug is sterile and pyrogen-free, as required by 21 C.F.R. § 211.167(a). Specifically, Defendants had not performed or recorded any bacterial endotoxin testing on any of their sterile drugs since February 20, 2017. Defendants also had not performed any sterility testing on their drugs that are terminally sterilized in the autoclave or dry heat oven. Defendants also did not follow United States Pharmacopoeia requirements for demonstrating that the method and media used in their in-house test for drug sterility were appropriate for detecting microbiological contamination.

D. Failure to perform any microbiological testing on non-sterile drugs to demonstrate that those drugs are free from objectionable organisms, as required by 21 C.F.R. § 211.165(b). Specifically, Defendants had not performed any microbial enumeration or specified microorganism testing on their non-sterile drugs prior to release.

E. Failure to establish and follow written procedures for cleaning and maintaining equipment used in the manufacture, processing, packing, or holding of a drug product, as required by 21 C.F.R. § 211.67(b), and failure to establish an adequate system for cleaning and disinfecting aseptic processing areas and equipment to produce aseptic conditions, as required by 21 C.F.R. § 211.42(c)(10)(v). Defendants cleaned drug processing equipment with a non-pharmaceutical grade household dishwashing detergent and did not verify that the detergent would not leave residue on the equipment. Defendants also failed to follow Guardian's standard operating procedure to rinse equipment with sterile water prior to it being placed in the dry heat oven for sterilization.

F. Failure to establish and follow a written testing program to establish and assess the stability characteristics of drug products, the results of which are used in determining appropriate storage conditions and expiration dates for drug products, as required by 21 C.F.R. § 211.166(a). During the 2018 Inspection, FDA investigators found that defendants had no scientific process for assigning or validating the Beyond Use Dates ("BUD") that they assign to their drugs, nor had they generated any scientific data for the BUDs that they assigned to their drugs. FDA investigators documented six different drugs with BUDs ranging from 14 to 180 days with no documentation to support the BUDs.

G. Failure to investigate the failure of a batch or any component to meet specifications, whether or not the batch has already been distributed, as required by 21 C.F.R. § 211.192. Specifically, in March 2017, Defendants received a customer complaint that one of their sterile drug products was "not working." Two samples from that lot failed potency testing; however, Defendants failed to investigate the reason for the product failure or to recall the remaining units in the batch, putting patients at risk of receiving ineffective drugs. In February 2017, Defendants could not verify the accuracy of their endotoxin testing due to the failure of internal test system controls during testing of one of Defendants' sterile drugs; however, Defendants did not investigate the failure and proceeded to distribute the drug. In September 2016, one of Defendants' purportedly sterile drug products failed sterility testing. Defendants initiated a recall, but failed to identify the microbial growth involved in the failure, determine the root cause of the failure, or take any subsequent corrective action to prevent future failures.

H. Failure to establish and follow written procedures for the handling of written and oral complaints related to drug products, as required by 21 C.F.R. § 211.198.

Specifically, Defendants logged 23 complaints in 2017, but the pharmacist-in-charge only reviewed four of these complaints, and no review or conclusion was reached for the other 19.

31. These observations establish that Defendants' drugs were adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacturing, processing, packing, or holding did not comply with CGMP to assure that they met the requirements of the Act as to their safety and that they had the identity and strength, and met the quality and purity characteristics, which they purported or were represented to possess.

32. Defendants violated 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

33. Defendants violated 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

Misbranding Due to False or Misleading Labeling

34. In May and December of 2017 and March 2018, FDA investigators collected drug product samples that Guardian had distributed to two eye surgery centers in connection with FDA's investigation into adverse event reports (see paragraph 54) and the 2018 Inspection. Two of the samples were labeled "PF," meaning preservative-free.

35. A subsequent laboratory analysis of these drug samples showed that each of them contained preservatives. Defendants' labeling for such drugs was false or misleading, and the drugs, therefore, were misbranded within the meaning of 21 U.S.C. § 352(a).

36. Defendants violated 21 U.S.C. § 331(k) by causing articles of drug intended to be preservative-free to become misbranded within the meaning of 21 U.S.C. § 352(a), while such drugs were held for sale after shipment of one or more of their components in interstate commerce.

Misbranding Due to Inadequate Directions for Use

37. Due to their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, Defendants' drugs are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. As such, these drugs are "prescription drugs" within the meaning of 21 U.S.C. § 353(b)(1)(A).

38. A prescription drug, by definition, cannot bear adequate directions for use by a layperson because such drug must be administered under the supervision of a licensed practitioner. *See* 21 U.S.C. § 353(b)(1). FDA has established certain exemptions from the requirement that labeling bear adequate directions for use (*see, e.g.*, 21 C.F.R. § 201.115); however, because Defendants' drug products were unapproved new drugs (see paragraphs 43-45), they did not bear adequate directions for use and, thus, did not satisfy the conditions for any of these exemptions.

39. Defendants' drug products were misbranded within the meaning of 21 U.S.C. § 352(f)(1).

40. Defendants violated 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drug that were misbranded within the meaning of 21 U.S.C. § 352(f)(1).

41. Defendants violated 21 U.S.C. § 331(k) by causing articles of drug to become misbranded, within the meaning of 21 U.S.C. § 352(f)(1), while such drugs were held for sale after shipment of one or more of their components in interstate commerce.

Unapproved New Drug Violations

42. During the 2018 Inspection, FDA observed that Defendants distributed drug products that lacked an approved NDA or ANDA, as required by 21 U.S.C. § 355, and were not exempt from approval pursuant to 21 U.S.C. § 355(i). These products are not generally recognized as safe and effective because there are no published adequate and well-controlled clinical studies of those drugs manufactured and distributed by Defendants for any indication. Therefore, they are new drugs within the meaning of 21 U.S.C. § 321(p).

43. Defendants' drug products were unapproved new drugs within the meaning of the Act, 21 U.S.C. § 355(a).

44. Defendants violated 21 U.S.C. § 331(d) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce new drugs that were neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

Defendants' Recent Representations

45. On May 15, 2018, Defendant Munn, on behalf of Guardian, agreed to voluntarily conduct a recall of all the company's sterile products within expiry. Guardian conducted the recall on May 17, 2018.

46. On May 31, 2018, Defendant Munn, on behalf of Guardian, agreed to voluntarily cease dispensing sterile compounded drugs for office use. Specifically, he stated that the company would cease dispensing compounded sterile drug products without patient-specific

prescriptions until "the issue of office use gets clarified and is fully allowable in Texas by all parties currently involved in the debate. . . ." So long as Guardian meets all the conditions of 21 U.S.C. § 353a for its compounded sterile drug products, including distributing compounded drug products pursuant to patient-specific prescriptions, it is exempt from the CGMP, new drug approval, and adequate directions for use requirements for its sterile drugs.

47. Defendant Munn has not represented that Guardian would cease dispensing non-sterile compounded drugs for office use. The company, therefore, is not exempt from the CGMP, new drug approval, and adequate direction for use requirements as they relate to its non-sterile compounded drugs that are dispensed for office use.

48. By letter dated June 8, 2018, Defendant Munn, on behalf of Guardian, responded to the 2018 FDA-483, outlining the corrective actions that Guardian intended to implement to alleviate the observed insanitary conditions. FDA thoroughly reviewed Guardian's documentation and determined that the corrective actions proposed, if correctly implemented and sustained, would alleviate most of the insanitary conditions cited in the 2018 FDA-483, but they do not alleviate the CGMP deficiencies cited in the 2018 FDA-483. FDA has not independently verified whether the proposed corrective actions have been correctly implemented and sustained.

49. On June 15, 2018, Defendant Munn agreed to cease compounding sterile drug products until the company had corrected the insanitary conditions observed by FDA.

Prior Inspections and Warnings to Defendants

50. FDA previously inspected Guardian between September 12 and October 21, 2016 (the "2016 Inspection") and observed numerous insanitary conditions and CGMP deficiencies, some of which were the same as those observed during the 2018 Inspection.

51. During the 2016 Inspection, FDA investigators observed and documented numerous insanitary conditions including, but not limited to: use of non-sterile wipes and non-sterile disinfectant in aseptic processing areas; a laminar air flow workbench in the cleanroom suite that is supported by particle board, which is difficult to disinfect; and failure to adequately simulate aseptic processes through media fills. FDA investigators also documented numerous serious deviations from the CGMP requirements during the 2016 Inspection including, but not limited to: failure to establish and follow appropriate written procedure for monitoring environmental conditions in the aseptic processing areas; failure to establish and follow appropriate written procedures, including validation of all aseptic and sterilization processes, designed to prevent microbial contamination of drug products purporting to be sterile; failure to establish and follow appropriate written procedures for testing drugs purporting to be sterile and/or pyrogen-free; failure to clean and disinfect equipment to prevent contamination; and failure to thoroughly review and investigate unexplained discrepancies and/or the failure of a batch or any component to meet any of its specifications, whether or not the batch has been distributed.

52. During the 2016 Inspection, FDA investigators also observed a sterility failure of a purportedly sterile drug product manufactured and distributed by Guardian for office use. On September 23, 2016, Guardian conducted a voluntary recall of certain sterile drug products within expiry due to lack of sterility assurance.

53. At the close of the 2016 Inspection, the FDA investigators provided an FDA-483 to Defendant Munn and discussed the inspectional observations with him.

54. FDA received adverse event reports on April 5 and June 1, 2017, concerning at least 43 patients treated at two Dallas-area eye surgery centers who experienced vision

impairment and loss after being administered intravitreal injections of a drug containing triamcinolone and moxifloxacin compounded by Defendants.

55. FDA issued Defendant Munn, as Guardian's owner, a Warning Letter on November 3, 2017, as a result of the 2016 Inspection, stating that investigators had "noticed serious deficiencies in [Guardian's] practices for producing sterile drug products, which put patients at risk." The Warning Letter stated Guardian produced adulterated drugs in violation of 21 U.S.C. § 351(a)(2)(A) because all of its drug products were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health. The Warning Letter also advised Defendants that certain compounded drug products were not eligible for the exemptions set forth in 21 U.S.C. § 353a due to Defendants' failure to receive valid prescriptions for individually identified patients for those drug products. Those drug products were, therefore, adulterated drugs in violation of 21 U.S.C. § 351(a)(2)(B) (concerning CGMP), misbranded drugs in violation of 21 U.S.C. § 352(f)(1) (concerning labeling with adequate directions for use), and unapproved new drugs in violation of 21 U.S.C. § 355(a). FDA advised Defendants that they "should take prompt action to correct the violations cited in this letter" and that "[f]ailure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction."

56. On November 13, 2017, Defendant Munn, on behalf of Guardian, replied to the Warning Letter reiterating that many of FDA's observations were based on CGMP, which Guardian was not legally required to follow, and outlining steps that Guardian would take to alleviate the insanitary conditions discussed in the FDA-483. By letter dated March 22, 2018, FDA replied to Defendant Munn that Guardian had failed to adequately address the CGMP violations and insanitary conditions that FDA observed during its 2016 Inspection. FDA also

repeated its prior warning that Guardian must meet the conditions of section 353a, including the requirement that compounding be based on the receipt of a valid prescription for an individually identified patient for its compounded drugs to qualify for the exemptions in 21 U.S.C. § 353a, including exemptions from CGMP, new drug approval, and adequate directions for use requirements. FDA further reminded Defendant Munn that failure to correct the violations may result in legal action without further notice, including, without limitation, injunction.

57. Despite further promises to correct their deficiencies, Defendants' violations persisted, as evidenced by the violations observed during FDA's 2018 Inspection.

58. Based on the foregoing, Plaintiff believes that, unless restrained by the Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Order that Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, cease manufacturing, processing, packing, labeling, holding, or distributing any article of drug unless and until Defendants bring their manufacturing, processing, packing, labeling, holding, and distribution operations into compliance with the Act and its implementing regulations to the satisfaction of FDA;

II. Order that Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing and/or causing to be introduced, and/or delivering or causing to be delivered for introduction, into interstate

commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and/or 351(a)(2)(B), and/or misbranded within the meaning of 21 U.S.C. §§ 352(a)(1) and/or 352(f)(1);

B. Violating 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and/or 351(a)(2)(B) and/or misbranded within the meaning of 21 U.S.C. §§ 352(a)(1) and/or 352(f)(1), while such drug is held for sale after shipment of one or more of its components in interstate commerce; and

C. Violating 21 U.S.C. § 331(d) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i), in violation of 21 U.S.C. § 355;

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections, including testing and sampling, to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Award Plaintiff costs and other such relief as the Court deems just and proper.

DATED this ___ day of _____, 2019.

Respectfully submitted,

ERIN NEALY COX
United States Attorney

JOSEPH H. HUNT
Assistant Attorney General

GUSTAV W. EYLER
Acting Director
Consumer Protection Branch

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